

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
SOUTHERN DIVISION  
NO. 7:23-CV-897**

**IN RE:**

**CAMP LEJEUNE WATER LITIGATION**

**This Document Relates To:**

**ALL CASES**

**MEMORANDUM OF LAW IN SUPPORT  
OF THE UNITED STATES' MOTION TO  
EXCLUDE CERTAIN PLAINTIFFS'  
GENERAL CAUSATION EXPERTS'  
TESTIMONY UTILIZING THE  
"AT LEAST AS LIKELY AS NOT"  
STANDARD**

## TABLE OF CONTENTS

	<u>Pages</u>
Table of Contents .....	1
Introduction.....	2
Background .....	4
Argument .....	6
I. Plaintiffs’ General Causation Experts Impermissibly Offered Legal Opinions in Violation of Rule 704 of the Federal Rules of Evidence .....	7
A. This Court Held that the CLJA’s Burden of Proof—“At Least as Likely as Not”—is the Legal Standard for This Court to Apply .....	10
B. The Policy-Based Origins of the CLJA’s “At Least as Likely as Not” Standard Confirm that It is Not a Scientific Standard, but a Legal One.....	12
C. This Court Should Exclude the Opinions of Plaintiffs’ General Causation Experts that Opine on the CLJA’s Ultimate Burden of Proof .....	14
II. Plaintiffs’ General Causation Experts Impermissibly Utilized the “At Least As Likely as Not” Legal Standard to Relax the Scientific Standards Otherwise Applied in Their Respective Disciplines and so Violated Rule 702.....	15
Conclusion .....	22
Certificate of Service .....	24

## INTRODUCTION

As this Court has held, the Camp Lejeune Justice Act of 2022 (“CLJA”) litigation is a modified toxic tort case. *See In re Camp Lejeune Water Litig.*, 736 F. Supp. 3d 311, 320 (E.D.N.C. 2024) (“Congress included common-law tort causation in the CLJA.”). As this Court noted, “[o]rdinarily, toxic exposure torts proceed in two steps—an expert demonstrates that a particular type of harm can be caused *by the exposure to a degree of scientific certainty (general causation)* and an expert opines that this plaintiff’s exposure was a cause in fact of his or her harm (specific causation).” *Id.* at 319 (citing Restatement (Third of Torts: Phys. & Emot. Harm § 26 cmt. (b); *Nix v. Chemours Co. FC*, No. 7:17-CV-189, 2023 WL 6471690, at \*8 (E.D.N.C. Oct. 4, 2023) (Dever, J.) (emphasis added)). Thus, Plaintiffs’ general causation experts should have applied the typical scientific standards of their respective disciplines when evaluating whether the chemicals in the water at Camp Lejeune could have caused the Track 1 illnesses. Instead, Plaintiffs’ general causation experts largely, and improperly, relied on the ultimate *legal burden* under the CLJA, and opined as to whether the chemicals were “at least as likely as not” to cause the Track 1 illnesses. Doing so violates both Federal Rule of Evidence 704—because it is impermissible opinion testimony stating a legal standard and drawing a legal conclusion, and Rule 702—because it relaxes, for litigation purposes, the scientific standards that are otherwise applied in epidemiology, toxicology, or related fields.

The “at least as likely as not” standard originated from a presumptive standard created by the Institute of Medicine (“IOM”), which is used by the U.S. Department of Veteran’s Affairs to determine if veterans are entitled to certain disability benefits. The Agency for Toxic Substances and Disease Registry (“ATSDR”) then adopted this standard when conducting a policy-based

analysis of the contaminants in the water at Camp Lejeune.<sup>1</sup> Eventually, Congress imported the “at least as likely as not” standard language into the CLJA and designated it as the ultimate evidentiary burden of proof for the Court to apply after considering all of the admissible evidence at trial. At no point did Congress abrogate, change, or relax the scientific standards that are used by general causation experts in their various disciplines. And as many of Plaintiffs’ experts testified, they themselves have never used the “at least as likely as not” standard in general causation analyses for toxic tort litigation, or in scientific publications more broadly.

As a result, Plaintiffs’ general causation experts have strayed from applying the appropriate scientific standards and usurped the Court’s role as factfinder by opining that Plaintiffs have met their legal burden under the CLJA. This is directly contrary to Rule 704.

Furthermore, use of the “at least as likely as not” burden in the general causation stage of this litigation is inappropriate. As explained below, “at least as likely as not” applies as the legal burden once all the admissible evidence has been examined by the Court. It was not meant to be utilized at every individual step of the litigation. By importing the “at least as likely as not” legal standard into their scientific analyses, Plaintiffs’ general causation experts deviated from established scientific methodologies and failed to apply the same intellectual rigor that they would in their various disciplines outside of litigation. This is exactly what Rule 702 forbids.

Plaintiffs’ general causation experts’ inappropriate use of the “at least as likely as not” legal standard violates Rules 702 and 704. As such, any general causation opinion predicated on the “at least as likely as not” legal standard should be excluded.

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<sup>1</sup> As discussed further below, ATSDR used the term “equipoise” to describe whether a finding was “at least as likely as not.” Some of Plaintiffs’ general causation experts also employ an “equipoise” standard, which is impermissible for the same reasons as the “at least as likely as not” standard.

## **BACKGROUND**

Almost all of Plaintiffs' Phase II experts opining on general causation impermissibly expressed their opinions in terms of the "at least as likely as not" evidentiary burden of the CLJA and applied an improperly relaxed standard to their evaluation of the scientific evidence. This is a tacit admission that Plaintiffs are unable to prove general causation using scientific standards with the same rigor that their general causation experts use outside the courtroom.

For example, Dr. Bird quoted the CLJA in his Parkinson's disease expert report and then immediately noted that, "[t]his standard has significant implications for the analysis at issue in this report . . . . The determination of a causal relationship is naturally different under a standard that requires a proof 'more likely than not,' as compared to a standard that requires a proof 'as likely as not.'" Bird GC Rep. (PD) at 6 (JA Ex. 118, [D.E. 467-1](#)). Similarly, Dr. Felsher stated in his report that he "understands 'at least as likely as not' to be the causation standard under the Camp Lejeune Justice Act." Felsher GC Rep. (NHL-Leuk) at 5 (JA Ex. 107, [D.E. 466-1](#)).

At deposition, Plaintiffs' experts testified that the standard employed in their reports originated from the CLJA and that counsel instructed them to use it in arriving at their opinions for this litigation. For example, Dr. Gondek confirmed that the "at least as likely as not" standard was from the CLJA and testified that Plaintiffs' Leadership Group ("PLG") "provided me with the Camp Lejeune Justice Act and the standard that I should form my opinion based on, which has made my interpretation or different standard at what [sic] we used to use in legal cases." Gondek GC Dep. Tr. at 249:16-250:10 (JA Ex. 160, [D.E. 469-14](#)). Dr. Cannon similarly testified that he was provided the CLJA by counsel and that he incorporated the "as likely as not" standard as "criteria" "specific to the statute." Cannon Dep. Tr. at 53:6-54:9 (JA Ex. 168, [D.E. 470-7](#)). Dr. Boehme also confirmed that the "at least as likely as not" language incorporated into her opinions on general causation came from the CLJA. Boehme Dep. Tr. at 327:18-328:7 (JA Ex. 167, [D.E.](#)

[470-6](#)). Dr. Felsher testified that he is “qualified to make a scientific opinion, and the scientific opinion I make can certainly [be] put in the context of the legal standard. Just as if a jury is told what the standard is to evaluate something, they’re told what the law is and then [they] make a determination.” Felsher GC Dep. Tr. at 18:9-21 (JA Ex. 164, [D.E. 470-3](#)). Dr. Gilbert similarly testified: “I took [the equipoise or ‘at least as likely as not’ standard] into consideration when I was looking at the material [by] [c]omparing whether a particular study met, or the cumulative exposures met that criteria.” Gilbert Dep. Tr. at 43:5-10 (JA Ex. 165, [D.E. 470-4](#)). Dr. Miller stated in his report that, “it is my professional opinion that TCE, is at least as likely as not, a cause of the pathogenesis and progression of Parkinson’s Disease.” Miller GC Rep. at 3-4 (JA Ex. 132, [D.E. 467-15](#)). When asked at deposition about this language, Dr. Miller testified,

I’m a scientist, I typically write in a scientific language. But I’m aware that there’s terms that are used in legal proceedings and this is one of the terms used when you are saying that you think it’s at least as likely as not, that part of it. That was the language I was using.

Miller GC Dep. Tr. at 169:8-13 (JA Ex. 171, [D.E. 470-10](#)).

In addition, Plaintiffs’ experts confirmed during their depositions that “at least as likely as not” is a legal standard, not a scientific standard that is used in the scientific community for determining causation. For example, Dr. De Miranda confirmed that to her knowledge, she had never used “as likely as not” in a report for litigation, had never read a scientific article that used the “as likely as not” standard, and that “as likely as not” is not the typical vernacular used in toxicological or scientific literature. De Miranda Dep. Tr. at 87:18-88:8 (JA Ex. 170, [D.E. 470-9](#)). Dr. Freeman has authored over 2,000 expert reports for litigation, and he testified to never having used the “at least as likely as not” standard in prior reports and never having used it in scientific publications. Freeman Dep. Tr. at 35:19-36:8; 283:6-10; 293:1-6 (JA Ex. 159, [D.E. 469-13](#)). When Dr. Hu was asked whether he had “interpreted a statute’s legal causation standard” in any prior

case in which he served as a general causation expert, Dr. Hu responded, “No.” Hu GC Dep. Tr. at 65:24-66:2 (JA Ex. 162, [D.E. 470-1](#)). Similarly, Dr. Gilbert testified that “equipoise is more of a legal term than a basic science term. So I don’t believe I’ve ever used it in my own basic science research.” Gilbert Dep. Tr. at 43:25-44:4 (JA Ex. 165, [D.E. 470-4](#)). Yet Plaintiffs’ experts employed the “at least as likely as not” standard even though, as Dr. Hatten admitted in his reports, “there is no universal consensus on how an at least ‘as likely as not’ standard is to be evaluated.” Hatten GC Rep. (Bladder) at 6 (JA Ex. 76, [D.E. 463-15](#)); Hatten GC Rep. (Kidney) at 6 (JA Ex. 90, [D.E. 464-11](#)). Dr. Costa was asked to define the “as likely as not” standard and testified that, “[w]ell, this is not my language in that in my profession we don’t use this type of language.” Costa Dep. Tr. at 40:21-22 (JA Ex. 169, [D.E. 470-8](#)). Dr. Hu testified that he was “not sure [equipoise has] ever been considered in the medical community.” Hu GC Dep. Tr. at 69:12-13 (JA Ex. 162, [D.E. 470-1](#)).

Despite these admissions, Plaintiffs’ experts used the “at least as likely as not” standard in their evaluation of the scientific evidence in this litigation. Indeed, the reports and depositions of Plaintiffs’ general causation experts are replete with similar admissions and statements concerning the “at least as likely as not” standard. The United States refers the Court to **Exhibit 1**, Compendium of Experts’ Use of “At Least as Likely as Not,” which contains a compendium of Plaintiffs’ experts’ use of the “at least as likely as not” standard.

### **ARGUMENT**

Plaintiffs’ general causation experts expressly imported the “at least as likely as not” legal standard into their scientific analyses concerning epidemiology, toxicology, and related scientific disciplines. That creates two problems.

First, such opinions improperly draw a legal conclusion—i.e., whether Plaintiffs have met their ultimate legal burden of proof under the CLJA. Opining on an ultimate legal conclusion is

generally inadmissible under the Fourth Circuit’s precedent interpreting Rule 704. Second, it renders their opinions unreliable under Rule 702.<sup>2</sup> By trying to use the “at least as likely as not” *legal* standard when purportedly conducting *scientific* analyses, Plaintiffs’ experts impermissibly relaxed the scientific standards that they would otherwise apply in their fields. Contrary to these experts’ use of a new standard for this case, Rule 702 and *Daubert* require that experts “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Accordingly, the United States asks this Court to exclude any general causation opinion predicated on the “at least as likely as not” legal standard.

**I. Plaintiffs’ General Causation Experts Impermissibly Offered Legal Opinions in Violation of Rule 704 of the Federal Rules of Evidence.**

Rule 704(a) provides that otherwise admissible opinion testimony “is not objectionable just because it embraces an ultimate issue.” Fed. R. Evid. 704(a). However, it “does not lower the bar so as to admit all opinions.” *Id.*, advisory committee’s notes (1972). Thus, “[o]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *Brainchild Surgical Devs., LLC v. CPA Global Ltd.*, 144 F.4th 238, 253 (4th Cir. 2025); *see also United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011); *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006); *United States v. Barile*, 286 F.3d 749, 759-60 (4th Cir. 2002); *Yates v. Ford Motor Co.*, No. 5:12-CV-752-FL, 2015 WL 3448905, at \*6 (E.D.N.C. May 29, 2015) (Flanagan, J.); *SMD Software, Inc. v. Emove, Inc.*, No. 5:08-CV-403-FL, 2014 WL

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<sup>2</sup> Relatedly, the burden of proof for admission of expert testimony is on the proponent of the expert to show admissibility under the standards of Rule 702 by a preponderance of the evidence, *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). The burden does not change based on the ultimate burden of proof in the case. *Compare United States v. Rouse*, No. 22-4479, 2024 WL 2044630 (4th Cir. May 8, 2024) (*per curiam*) (beyond all reasonable doubt), *with Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 198 (4th Cir. 2001) (more likely than not).



1807809, at \*1-2 (E.D.N.C. May 7, 2014) (Flanagan, J.); *HBC Ventures, LLC v. Holt MD Consulting, Inc.*, No. 5:06-CV-190-F, 2012 WL 4483625, at \*7-10 (E.D.N.C. Sept. 27, 2012) (Fox, J.); *United States v. Freedman Farms, Inc.*, No. 7:10-CR-15-FL, 2011 WL 2534114, at \*4-6 (E.D.N.C. June 27, 2011) (Flanagan, J.).

For example, experts cannot express opinions about: (1) the meaning of a contract, *see Brainchild Surgical Devs., LLC*, 144 F.4th at 253-54; (2) the applicable legal standards for damages in Lanham Act cases, *SMD Software, Inc.*, 2014 WL 1807809, at \*2; (3) a defendant's guilt or innocence in a criminal case, 4 Weinstein's Federal Evidence § 704.04 (2025); or (4) a defendant's negligence in a tort case. *Id.* "Stated another way, 'opinions which would merely tell the [factfinder] what result to reach' are inadmissible." *SMD Software*, 2014 WL 1807809, at \*1 (quoting Rule 704 advisory committee note). And while there is a narrow exception in "complex and highly technical cases," *see Brainchild Surgical Devs., LLC*, 144 F.4th at 254, it does not apply here. The Court is well able to apply the CLJA's "at least as likely as not" standard, given that it has handled other toxic tort litigation. *See generally Conklin v. Corteva, Inc.*, No. 7:23-CV-1114-D, 2025 WL 1402696 (E.D.N.C. May 14, 2025); *In re Panacryl Sutures Prods. Liab. Cases*, 263 F.R.D. 312 (E.D.N.C. 2009).

"The best way to determine whether opinion testimony contains legal conclusions, is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular." *Yates*, 2015 WL 3448905, at \*6 (quoting *Barile*, 286 F.3d at 760). To do so, the Court "should consider *first* whether the question

tracks the language of the legal principle at issue or of the applicable statute, and *second*, whether any terms employed have specialized legal meaning.” *Id.* (emphasis added).<sup>3</sup>

Determining whether terms have specialized legal meanings is critical to whether an expert has used the proper standard in formulating their opinions. As Dr. David Savitz, another one of Plaintiffs’ experts, acknowledged in his book, *Epidemiology and the Law*:

The level of certainty required for confidently asserting causality in epidemiology is arguably analogous to the criminal burden of proof of beyond a reasonable doubt. Conversely, in an individual civil lawsuit, the issue is whether the alleged agent more probably than not caused the damages suffered, a difficult standard for epidemiology experts to address. Thus, causation can mean very different things within the field of epidemiology and the law, and translating from one to the other can be difficult.

David Savitz, *Epidemiology and the Law* 3 (2023). Or, as David Goodstein eloquently stated in the *Reference Manual on Scientific Evidence*:

Oscar Wilde (and G.B. Shaw too) once remarked that the United States and England are two nations divided by a common language. Something similar can be said, with perhaps more truth (if less wit), of science and the law. There are any number of words commonly used in both disciplines, but with different meanings.

David Goodstein, *Reference Manual on Scientific Evidence: How Science Works*, 51 (The National Academies Press, 3d ed. 2011), available at <https://doi.org/10.17226/13163> (last visited September 8, 2025). Here, “at least as likely as not” has a specialized legal meaning for the Court—not scientific experts—to consider.

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<sup>3</sup> See also *United States v. Campbell*, 963 F.3d 309, 315 (4th Cir. 2020); *McIver*, 470 F.3d at 562 (“We identify improper legal conclusions by determining whether ‘the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.’”); *Barile*, 286 F.3d at 760; *Burkhart v. Wash. Metro. Area Transit Auth.*, 112 F.3d 1207, 1212 (D.C. Cir. 1997) (testimony was an impermissible legal conclusion where it tracked the language of Title VII and the term “discrimination” had a specialized legal meaning).

**A. This Court Held that the CLJA’s Burden of Proof—“At Least as Likely as Not”—is the Legal Standard for This Court to Apply.**

There can be no doubt that the CLJA’s burden of proof (i.e., at least as likely as not) is the legal standard for this Court to apply after considering all of the admissible evidence at trial. The CLJA expressly provides that the “at least as likely as not” standard applies as the burden of proof:

(b) Burdens and standard of proof.—

(1) IN GENERAL.—The burden of proof shall be on the party filing the action to show one or more relationships between the water at Camp Lejeune and the harm.

(2) STANDARDS.—To meet the burden of proof described in paragraph (1), a party shall produce evidence showing that the relationship between exposure to the water at Camp Lejeune and the harm is—

(A) sufficient to conclude that a causal relationship exists; or

(B) sufficient to conclude that a causal relationship is at least as likely as not.

See CLJA, Pub. L. No. 11-168, § 804(b).<sup>4</sup> There is no indication within this Section that Congress intended for the “at least as likely as not” standard to apply to the Court’s intermediary evaluations on issues like general causation.

Indeed, in its Order denying PLG’s Motion for Partial Summary Judgment on the Issue of Specific Causation, this Court held that “Congress included common-law tort causation in the CLJA.” See *In re Camp Lejeune Water Litig.*, 736 F. Supp. 3d at 320. The Court recognized that the “at least as likely as not standard” is the burden of proof under the CLJA. But the Court further found that “Congress’s express alteration of the burden of proof in subsection 804(c) does not demonstrate Congress’s intent to replace the common-law causation framework.” *Id.* at 323. In its decision, this Court made clear that “[t]he causal framework for a CLJA claim and the burden of proof applicable to that framework are interlocking parts, but *Congressional change to one portion*

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<sup>4</sup> For a more fulsome discussion of the legislative history of the CLJA, see United States’ Response to PLG’s Motion for Partial Summary Judgment on the Issue of Specific Causation, [D.E. 139](#).

*does not necessitate a change to the other.*” *Id.* at 324 (emphasis added). As applied here, a change to the burden of proof does not mean a change to the scientific standards experts typically employ.

This Court further explained that the phrase “at least as likely as not” “pertains to burdens of proof, not causation.” *Id.* at 325. The Court’s opinion on specific causation made clear that “at least as likely as not” was the proper *legal burden* to be applied in this litigation. In addition, whether an individual has established that his or her alleged harm was caused “at least as likely as not” by exposure to contaminated water at Camp Lejeune, as required by the statute, is determined by applying the standard to the entirety of the evidence, not at each phase of causation. This is because, as this Court explained, “[t]he separation of causation into exposure, general causation, and specific causation is an exercise designed to ensure that issues of causation simpliciter are fully considered. They are not separate ‘elements’ of a CLJA claim. Causation subsumes all three.” *Id.* at 319 (citing *Cause*, Black’s Law Dictionary (11th ed. 2019) and Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt. (c)(1)). Logically, the burden of proof is to be applied by the trier of fact at the *conclusion* of all of the parties’ facts and evidence at trial. *Silver State Solar Power S., LLC v. United States*, No. 18-266T, 2020 WL 6139865, at \*6 (Fed. Cl. Oct. 19, 2020); *see also Rouse*, 2024 WL 2044630, at \*1 (preponderance of the evidence standard applies to admissibility determinations under *Daubert* in a criminal case where the ultimate burden of proof is beyond a reasonable doubt). The plain language of the CLJA does not support PLG’s apparent position that the modified legal standard should be applied separately at each showing of proof. If Congress had intended to apply the modified legal burden of proof in a different manner than it is applied in typical tort cases, it could have done so.

**B. The Policy-Based Origins of the CLJA’s “At Least as Likely as Not” Standard Confirm that It is Not a Scientific Standard, but a Legal One.**

The policy-based origins of the CLJA’s “at least as likely as not” standard further confirm that it is a legal standard, not a scientific one that exists within epidemiology, toxicology, or other related scientific disciplines. ATSDR’s uses of “equipoise and above” or “at least as likely as not” in its 2017 “Assessment of the Evidence for Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases” (“Assessment of the Evidence”) grew out of policy making and presumptions related to veteran benefits. *See, e.g., Exhibit 2*, Oct. 17, 2024 Bove. Dep. Tr., at 104:13-106:25; 115:23-116:2; ATSDR 2017 Assessment at 6-7 (JA Ex. 182, D.E. [472-3](#)).

A 2008 report published by the IOM explained that “[p]resumptions are made when there are gaps in the information related to exposure and causal classification” including “incomplete scientific evidence as to whether an exposure during service causes the health condition of concern.” IOM, *Improving the Presumptive Disability Decision-Making Process for Veterans* (Nat’l Academs. Press, 2008), at 1, 138, <https://nap.nationalacademies.org/read/11908/chapter/1> (last accessed Sept. 8, 2025) [hereinafter “IOM Report”]. Specifically, the IOM Report stated that “[p]resumptions have been made to relieve veterans of the burden to prove that disability or illness was caused by a specific exposure that occurred during military service.” *Id.* at 10.

Against this policy-driven backdrop, the IOM committee developed a classification scheme for presumptive decision-making. The IOM committee proposed four categories to characterize the strength of the evidence for or against a causal relationship for presumptive decision-making at the administrative level: (1) Sufficient; (2) Equipoise and Above; (3) Below Equipoise; and (4) Against. *See id.* The IOM Report concluded that “the scientific community should categorize the overall evidence as making it more confident in the existence of a causal

relationship than in the non-existence of a causal relationship, *but not sufficient to conclude causation.*” *Id.* at 191 (emphasis added).

In 2017, ATSDR’s Assessment of the Evidence used the same categories that the IOM had used for presumptive policy-based decision-making. Dr. Frank Bove was the sole author of the Assessment of the Evidence and drafted it by himself in six weeks. See **Exhibit 2**, Oct. 17, 2024 Bove. Dep. Tr., at 104:13-106:25 (“most of the tables you see in here were done within that six-week period”). As Dr. Bove testified in this litigation, the Assessment of the Evidence was written because “the VA decided, with a lot of pressure being put on them, to list kidney cancer, acute myeloid leukemia, and angiosarcoma of the liver as the three presumptive diseases that they wanted to [list as presumptive illnesses for awarding benefits in relation to a veteran’s time at Camp Lejeune]. And that was not acceptable to the CAP<sup>5</sup> or to the three senators [involved].” *Id.* at 105:12-20.

Dr. Bove testified that he chose the “Classification of Evidence” in the Assessment of the Evidence to weigh whether he believed a presumption should be made regarding certain illnesses. As Dr. Bove testified, he “thought the best thing to do was to do what the VA should do, which is give the benefit of doubt to the [veteran]. . . . And so equipoise made sense.” *Id.* at 115:23-116:2. The Assessment of the Evidence stated that “[t]his scheme makes clear when the evidence for causality is ‘at least as likely as not’ or at the level of ‘equipoise and above.’” ATSDR 2017 Assessment at 5 (JA Ex. 182, [D.E. 472-3](#)). The Assessment of the Evidence defined “Equipoise and Above” in its “classification scheme” as “[t]he evidence is sufficient to conclude that a causal

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<sup>5</sup> The “CAP” is the Community Assistance Panel, which is comprised of “Marines and their families to provide input on ATSDR’s public health activities.” *Community Assistance Panel (CAP)*, <https://www.atsdr.cdc.gov/camp-lejeune/community-assistance-panel/index.html> (last visited Sept. 8, 2025).

relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.” *Id.* at 6. But this was a standard for presumptive policy-based decision-making, not for evaluating evidence of causation under a methodology that produced scientifically reliable results pursuant to a legal standard like Rule 702.

After the passage of the CLJA, in 2023, the National Academies of Sciences, Engineering and Medicine (“NASEM”) reviewed the VA presumptive decision-making framework and the use of “at least as likely as not” and concluded: “[T]he term “equipoise” denotes a lack of consensus across the medical community and . . . the term as required by law to be used in the presumption decision process is inconsistent with the current scientific use of it.” NASEM, *Review of the Department of Veterans Affairs Presumption Decision Process* (2023), at 10, available at <https://nap.nationalacademies.org/catalog/27166/review-of-the-department-of-veterans-affairs-presumption-decision-process> (last visited Sept. 8, 2025).<sup>6</sup>

**C. This Court Should Exclude the Opinions of Plaintiffs’ General Causation Experts that Opine on the CLJA’s Ultimate Burden of Proof.**

Taken together, the plain language of the CLJA’s burden of proof, as previously interpreted by this Court, and the policy-based origins of the “at least as likely as not” standard satisfy the two-part analysis articulated in *Yates*, 2015 WL 3448905, at \*6 (The court “should consider first whether the question tracks the language of the legal principle at issue or of the applicable statute, and second, whether any terms employed have specialized legal meaning.”). First, many of Plaintiffs’ experts explicitly used the “at least as likely as not” language in their opinions, which applies the legal burden of proof in the CLJA to a strictly scientific determination. *See, e.g.*, Felsher

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<sup>6</sup> Plaintiffs’ expert Dr. Mallon confirmed that “equipoise” “is used in VA decision-making regarding disability determinations for veterans’ disability claims. That’s the current law. And that’s where it’s used . . . particularly for guidance for physician medical review officers.” Mallon GC Dep. Tr. at 56:10-16 (JA Ex. 151, [D.E. 469-5](#)).

GC Rep. (NHL-Leuk) at 5 (JA Ex. 107, [D.E. 466-1](#)); Gondek GC Dep. Tr. at 249:16-250:10 (JA Ex. 160, [D.E. 469-14](#)); Cannon Dep. Tr. at 53:6-54:9 (JA Ex. 168, [D.E. 470-7](#)). Second, “at least as likely as not” has a specialized legal meaning, regardless of how it is considered for presumptive policy-based judgments. This is evident not only in the policy-based history of the phrase, but also in the testimony of Plaintiffs’ own experts that they have not used the standard in their scientific practices. *See, e.g.*, De Miranda Dep. Tr. at 87:18-88:8 (JA Ex. 170, [D.E. 470-9](#)); Freeman Dep. Tr. at 35:19-36:8, 283:6-10, 293:1-6 (JA Ex. 159, [D.E. 469-13](#)); Hu GC Dep. Tr. at 65:24-66:3 (JA Ex. 162, [D.E. 470-1](#)); Gilbert Dep. Tr. at 42:17-44:4 (JA Ex. 165, [D.E. 470-4](#)).

Thus, Plaintiffs’ experts’ use of the “at least as likely as not” standard improperly states legal conclusions, invades on the province of the factfinder, and will not be helpful to the Court. Accordingly, those opinions should be excluded under Rule 704 and the Fourth Circuit’s general prohibition on opinion testimony that states a legal standard or draws a legal conclusion.

**II. Plaintiffs’ General Causation Experts Impermissibly Utilized the “At Least As Likely as Not” Legal Standard to Relax the Scientific Standards Otherwise Applied in Their Respective Disciplines and so Violated Rule 702.**

Not only does Plaintiffs’ general causation experts’ use of the “at least as likely as not” legal standard run afoul of Rule 704, it also renders their general causation opinions unreliable and therefore inadmissible under Rule 702. Rule 702 governs “whether an expert opinion *should be admitted* in the first place . . . .” *Campbell*, 963 F.3d at 313-14 (citations omitted) (emphasis in the original). Under Rule 702, an expert’s testimony is reliable only if the party offering the expert testimony “demonstrates to the court that it is more likely than not” that the testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) “is based upon sufficient facts or data,” (3) “is the product of reliable principles and methods,” and (4) “reflects a



reliable application of the principles and methods to the facts of the case.” Fed. R. Evid. 702(a)-(d).

Rule 702 “permits an expert to give opinions on scientific matters, technical matters, or matters involving other specialized knowledge so long as the testimony ‘*will assist the trier of fact* to understand the evidence or to determine a fact in issue.’” *SMD Software, Inc.*, 2014 WL 1807809, at \*1-2 (quoting *Offill*, 666 F.3d at 175) (emphasis in original). “[T]he requirements of Rule 702 are not relieved merely because the court is the fact-finder.” *NAPCO, Inc. v. Landmark Tech. A, LLC*, 2023 WL 5000756, at \*15 n.5 (M.D.N.C. Aug. 4, 2023)) (citing *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832-33 (3d Cir. 2020) (“Rule 702 applies whether the trier of fact is a judge or a jury. By using the term ‘trier of fact,’ rather than specifying judge or jury, Rule 702 does not distinguish between proceedings.”)).

Under Rule 702, experts must use reliable methodology. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). If the expert’s methodology was “developed . . . expressly for the purpose of testifying” and is not a part of the expert’s non-litigation practice, that factor may weigh in favor of exclusion. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 920 (D.S.C. 2016); *see also In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 440 (S.D.N.Y. 2016), *aff’d*, 713 Fed. Appx. 11, 15 (2d Cir 2017) (affirming trial court’s exclusion of experts in part because they “lacked pre-litigation expertise” and “developed their theories for the purposes of this litigation”). Experts must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.

This is precisely what Plaintiffs’ general causation experts failed to do. Specifically, as their testimony makes clear, they were instructed by the attorneys to employ the “at least as likely

as not” legal standard in forming their opinions. *See, e.g.*, Miller GC Dep. Tr. at 168:7-19 (JA Ex. 171, [D.E. 470-10](#)) (“Q: And what does ‘as likely as not’ mean in that statement? A: Oh, ‘as likely as not’ means as described, it’s the majority by just the smallest amount. That language, my understanding from . . . the standard set in this case. Q: Are you referring to the Camp Lejeune Justice Act? A: Justice Act, sorry, yes. Q: And was that provided to you by counsel? A: Yes.”). Further, Plaintiffs’ experts did not attempt to explain the meaning of the standard in their reports. Rather, many simply copied the CLJA standard into their reports and did not meaningfully explain what the standard means—because they cannot. *See, e.g.*, Hu GC Rep. at 8 (JA Ex. 111, [D.E. 466-5](#)); Mallon GC Rep. (Kidney) at 7 (JA Ex. 92, [D.E. 464-13](#)); Hatten GC Rep. (Kidney) at 5-7 (JA Ex. 90, [D.E. 464-11](#)) (stating that there are proposed “approaches to operationalize the ‘as likely as not’ standard” but admitting “there is no universal consensus on how an at least ‘as likely as not’ standard is to be evaluated”).

In addition, many of Plaintiffs’ experts testified that they had not used “at least as likely as not” outside of the current litigation. *See, e.g.*, Gondek GC Dep. Tr. at 250:18-21 (JA Ex. 160, [D.E. 469-14](#)) (Q: You have not used the phrase ‘at least as likely as not’ in any of your scientific papers, have you? A: No. I think that’s the legal statute.”); Gilbert Dep. Tr. at 41:14-17 (JA Ex. 165, [D.E. 470-4](#)) (“Equipoise as far as I understand is more of a legal term than a scientific term. And no, I have never used that.”); Bird GC Dep. Tr. at 61:21-62:2 (JA Ex. 148, [D.E. 469-2](#)) (“Q: Are you aware of any published guidelines on how to apply the ‘as likely as not’ standard to scientific evidence? A: I don’t recall seeing that anywhere.”); Hu GC Dep. Tr. at 65:24-66:2 (JA Ex. 162, [D.E. 470-1](#)) (“Q: In any case in which you’ve served as a general causation expert, have you interpreted a statute’s legal causation standard? A: No.”); Miller GC Dep. Tr. at 169:20-24 (JA Ex. 171, [D.E. 470-10](#)) (“Q: Do you have any scientific articles published that incorporate at

least as likely as not as the standard? A: I would not use that terminology in a scientific manuscript.”). Plaintiffs’ general causation experts’ improper use of the CLJA’s ultimate burden of proof renders their methodology inherently unreliable.

For example, Plaintiffs’ general causation experts’ application of the “at least as likely as not standard” is inconsistent with the Bradford Hill framework that many of them also claim to follow in their analysis. The first step in applying a Bradford Hill analysis is determining whether an association exists at all. And the Bradford Hill criteria should only be used to establish causation after an association “is perfectly clear-cut and beyond what we would care to attribute to the play of chance.” *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 678 (M.D.N.C. 2003) (quoting Sir Bradford Hill, *The Environment and Disease: Association or Causation*, 58 *Proc. Royal Soc’y Med.* 295, 295–300 (1965)). But applying an “at least as likely as not” standard to whether an association exists to begin the Bradford Hill analysis is inconsistent with what the analysis itself requires. An association that is “at least as likely as not”—which many of these experts take to mean a 50-50 comparison<sup>7</sup>—is *not* “perfectly clear-cut and beyond what we would care to attribute to the play of chance.” This is plainly lowering the scientific standard normally applied in epidemiology (i.e., the so-called Bradford Hill factors) for litigation purposes. *See, e.g.*, *Costa Dep. Tr.* at 211:12-24 (JA Ex. 169, [D.E. 470-8](#)) (testifying he could apply Bradford-Hill because “the exposure could be as likely as not associated with [Parkinson’s Disease]”). By incorporating the “at least as likely as not” finding into all aspects of their analyses, Plaintiffs’ experts are misapplying standard scientific methodologies and failing to use “the same level of intellectual

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<sup>7</sup> *See, e.g.*, *Bird GC Dep. Tr.* at 221:20-222:2 (JA Ex. 148, [D.E. 469-2](#)) (“Q. Do you equate ‘equipoise and above’ with ‘as likely as not’? A. ‘Equipoise and above’ to me means ‘as likely as not or greater.’ ‘As likely as not’ means to me 50/50.”).

rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152. As a result, their general causation methodologies are unreliable.

Instead of shoehorning in the “at least as likely as not” standard into their analysis, Plaintiffs’ experts should have used the typical standards employed in their disciplines and analyzed whether, under those standards, the contaminants of concern can cause the Track 1 illnesses “to a reasonable degree of scientific certainty.” *See Riggins v. SSC Yanceyville Operating Co., LLC*, 800 F. App’x 151, 155-56 (4th Cir. 2020) (“Under binding Fourth Circuit precedent, for the question of causation to reach the [factfinder] in a medical malpractice case, a medical expert’s causation opinion must rise to the level of a ‘reasonable degree of medical certainty’ . . . .” (quotation omitted) (cleaned up)). “This evidentiary standard is ‘not merely one of semantics.’” *Id.* at 156 (quoting *Fitzgerald v. Manning*, 679 F.2d 341, 346 (4th Cir. 1982)). Rather, it is “essential.” *Id.* Indeed, the Court has clearly stated that “[o]rdinarily, toxic exposure torts proceed in two steps—an expert demonstrates that a particular type of harm can be caused *by the exposure to a degree of scientific certainty (general causation)* and an expert opines that this plaintiff’s exposure was a cause in fact of his or her harm (specific causation).” *In re Camp Lejeune Water Litig.*, 736 F. Supp. 3d 311 at 319 (citing Restatement (Third of Torts: Phys. & Emot. Harm § 26 cmt. (b); *Nix v. Chemours Co. FC*, No. 7:17-CV-189, 2023 WL 6471690, at \*8 (E.D.N.C. Oct. 4, 2023)) (emphasis added).

This is the standard used by the United States’ general causation experts in this case. *See, e.g.,* Goodman Rep. (PD) at 136 (JA Ex. 134, [D.E. 467-17](#)) (“Based on the currently available evidence, I conclude, to a reasonable degree of scientific certainty, that TCE, PCE, benzene, vinyl chloride, and *trans*-1,2-DCE in Camp Lejeune drinking water did not cause [Parkinson’s

disease].”);<sup>8</sup> Shields Rep. at 7 (JA Ex. 135, [D.E. 468-1](#)) (“The following opinions I hold to a reasonable degree of medical and scientific certainty.”). Doing so is consistent with the scientific standard used in the Fourth Circuit. Indeed, failure to use the “reasonable degree of scientific certainty” standard has resulted in exclusion of experts’ opinions. *See, e.g., Johnson v. DePuy Syntheses Prods., Inc.*, No. 1:21-cv-00025-MR-WCM, 2022 WL 1598797, at \*5 (W.D.N.C. May 19, 2022) (excluding expert because, *inter alia*, he did not provide “any causation opinion to a reasonable degree of scientific certainty”); *Zellars v. NexTech Ne., LLC*, 895 F. Supp. 2d 734, 750 (E.D. Va. 2012) (Expert could not “testify within a reasonable degree of scientific certainty what the minimum level of [plaintiff’s] exposure would need to be in order to cause her physical condition . . . . Without reliable scientific knowledge of what level of exposure to [the contaminant] is needed to produce the medical condition suffered by [plaintiff], [the expert] can only speculate whether the level of [plaintiff’s] exposure was high enough to cause her condition. Any opinion by [the expert] about whether [plaintiff’s] condition was consistent with the health effects of overexposure is either speculative or irrelevant, and therefore cannot be admitted under Rule 702.”), *aff’d* (4th Cir. 12-2267) (July 17, 2013) (unpublished).

Notably, one of Plaintiffs’ experts, Dr. Michael Freeman, has been excluded from

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<sup>8</sup> In the policy-context, the United States’ expert epidemiologist and toxicologist, Dr. Julie Goodman, published a policy-focused review and employed the same policy-based standard used by ATSDR’s Assessment of the Evidence, discussed on pages 12-14, above. *See* Goodman, Julie E., et al., *Short-term ozone exposure and asthma severity: Weight-of-evidence analysis*, Environmental Research 160 (2018) 391–97 (attached as **Exhibit 3**). There, the Environmental Protection Agency (“EPA”) had performed a review of the National Ambient Air Quality Standards for ozone and Dr. Goodman and her coauthors considered whether the weight-of-the-evidence supported EPA’s *policy* conclusions. *Id.* at 392. The authors concluded that the evidence only met the “equipoise and above” standard for policymaking purposes because there was equal likelihood of a causal relationship and not a causal relationship. *Id.* at 395. The authors cautioned that “[t]he substantial uncertainty in the body of evidence should be taken into consideration when this evidence is used for policymaking.” *Id.* at 396.

testifying because, *inter alia*, he took it upon himself to determine which scientific standard should apply in light of legal principles. In *Porter v. SmithKline Beecham Corp.*, 2015 WL 5970639 (Pa.Com.Pl. Oct. 05, 2015), Dr. Freeman offered opinions on general and specific causation.<sup>9</sup> The court in *Porter* found that Dr. Freeman “believes a ‘reasonable degree of scientific certainty’ is different in the scientific field of epidemiology from the ‘field’ of forensic epidemiology. Dr. Freeman testified that the legal standard of ‘more probable than not’ is his definition of ‘reasonable scientific certainty’ and that this standard varies by jurisdiction.” *Id.* When specifically asked during the *Porter* case whether there is “a scientific standard that’s the same across state lines,” Dr. Freeman answered, “No, it is not.” *Id.* The court disagreed and held that “*only a legal standard depends on jurisdiction and proper scientific methodology and conclusions do not vary* whether testified to on the Pennsylvania side or the New Jersey side of the Benjamin Franklin Bridge.” *Id.* (emphasis added). Based on these and other flaws, the court excluded Dr. Freeman’s testimony. *Id.* at 10.<sup>10</sup>

As *Porter* makes clear, it is improper for experts to attempt to mix legal burdens of proof with scientific standards and methodologies in fields such as epidemiology. Rather, a scientific

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<sup>9</sup> The case was in Pennsylvania state court, which applies *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), instead of *Daubert*. As such, the Pennsylvania court applied the *Frye* test. However, the court’s analysis in *Porter* is instructive on this point.

<sup>10</sup> Dr. Freeman uses the “at least as likely as not” standard in his reports here: “the Camp Lejeune Justice Act of 2021 [sic] specified that claimants who file in court are entitled to a standard of proof lower than the preponderance-of-the-evidence standard typically used in tort cases and that they need only show that ‘*a causal relationship is at least as likely as not*’ corresponding to the ATSDR classification “Equipoise and above.” Freeman Rep. (PD) at 22 (JA Ex. 131, [D.E. 467-14](#)) (emphasis in original).

expert should only be permitted to opine on scientific evidence using scientific standards.<sup>11</sup>

Because Plaintiffs' general causation experts improperly used a legal burden as their scientific standard, those opinions phrased in terms of "at least as likely as not" should be excluded under Rules 702 and 704. *See Campbell*, 963 F.3d. at 314 (whether the testimony assists the trier of fact is the "touchstone" of Rule 702); *McIver*, 470 F.3d at 562 ("opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible" under Rule 704); *Barile*, 286 F.3d at 760 ("Expert testimony that merely states a legal conclusion is less likely to assist the jury in its determination.")).<sup>12</sup>

### **CONCLUSION**

Based on the foregoing, the United States asks this Court to grant this Motion and to exclude all general causation opinions that are predicated on the "at least as likely as not" legal standard in the CLJA.

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<sup>11</sup> Dr. Freeman apparently still believes that a case's jurisdiction should dictate the standard employed by a scientific expert, as was demonstrated in his deposition testimony in this case. Freeman Dep. Tr. at 292:3-20 (JA Ex. 159, [D.E. 469-13](#)) ("Q: [Do] you believe the appropriate standard for a scientific conclusion in the field of forensic epidemiology depends on the jurisdiction? . . . A. It depends on what the statutory language is for that particular jurisdiction. Q. So it could differ between two cases you're an expert witness on, is that fair? A. Certainly. If you're talking about, for example, California law. Substantial factor causation is quite a bit different, the preponderance of evidence, but it is defined statutorily.").

<sup>12</sup> Although the Camp Lejeune trials will be conducted as bench trials, the principles behind maintaining a separation between the expert's opinion and the finder of fact's ultimate charge still apply. *NAPCO*, 2023 U.S. Dist. LEXIS 135580, at \*15 n.5. Furthermore, the requirement that an expert provide helpful opinions to the trier of fact also applies in a bench trial. Otherwise, the expert's opinions could constitute a waste of the court's time. *See, e.g., Schultz v. Butcher*, 24 F.3d 626, 632 (4th Cir. 1994) ("excluding relevant evidence in a bench trial because it is cumulative or a waste of time is clearly a proper exercise of the judge's power") (citation omitted).

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### **CERTIFICATE OF SERVICE**

I hereby certify that on September 10, 2025, I electronically filed the foregoing using the Court's Electronic Case Filing system, which will send notice to all counsel of record.

/s/ Sara J. Mirsky  
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